

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8624

Bartle, C.J.

March 9, 2011

The Estate of Sharon M. Drowns ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify Diet Drug Recipients for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. &

(continued...)

To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician, who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In August, 2006, Janet M. Tracy, Representative of the Estate, submitted a completed Green Form to the Trust signed by the attesting physician, Manoj R. Muttreja, M.D. Based on an echocardiogram dated November 27, 2001, Dr. Muttreja attested in Part II of the Green Form that Sharon M. Drowns ("decedent" or "Ms. Drowns") suffered from moderate mitral regurgitation, mitral

2. (...continued)

IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

annular calcification,⁴ pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. Based on such findings, the Estate would be entitled to Matrix B-1, Level V benefits in the amount of \$195,789.⁵

The Estate also submitted reports of echocardiograms dated November 27, 2001 and December 14, 2004. In the report of the November 27, 2001 echocardiogram, the reviewing cardiologist, Marc S. Shalek, M.D., measured decedent's mitral regurgitation to be 33%. In the report of the December 14, 2004 echocardiogram, the reviewing cardiologist, Ricky D. Latham, M.D., found "moderate mitral regurgitation." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA")

4. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).

5. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V benefits if the Diet Drug Recipient qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b).

in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2006, the Trust forwarded the claim for review by Zuyue Wang, M.D., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation based on the November 27, 2001 echocardiogram because it demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Wang stated, "The RJA/LAA was 13%. This RJA encircled should not include the area of low velocity flow." In addition, Dr. Wang determined that there was no reasonable medical basis for the attesting physician's finding that Ms. Drowns suffered from ventricular fibrillation or sustained ventricular tachycardia which resulted in hemodynamic compromise. Dr. Wang explained:

Claimant had 2 episodes of 4-6 beat asymptomatic, monomorphic nonsustained [ventricular tachycardia]. [Patient's] [blood pressures] were normal at the time of [ventricular tachycardia] which were documented by the A line and cuff pressure on the telemetry strips. [Ventricular tachycardia] was mostly due to ischemic cardiomyopathy in the post [coronary artery bypass graft] setting.⁶

6. Dr. Wang also concluded that the November 27, 2001 echocardiogram demonstrated an abnormal left atrial dimension and a reduced ejection fraction in the range of 50% to 60%. Dr. Wang also found that Ms. Drowns suffered from pulmonary hypertension with a peak systolic pulmonary artery pressure greater than 45 mm. Based on her finding that Ms. Drowns only suffered from mild mitral regurgitation, however, Dr. Wang opined that her pulmonary hypertension was not secondary to moderate or greater mitral

(continued...)

Although Dr. Wang indicated on the Attestation of Auditing Cardiologist that she reviewed both echocardiograms, she did not set forth any findings with respect to the December 14, 2004 echocardiogram.

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying the Estate's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁷ In contest, the Estate argued that there was a reasonable medical basis for Dr. Muttreja's finding that Ms. Drowns suffered from moderate mitral regurgitation and ventricular fibrillation. In support, the Estate submitted a declaration from Dr. Muttreja, who declared, in pertinent part, that:

2. I reviewed a copy of the above-referenced Claimant's echocardiogram videotape dated November 27, 2001.

3. On this videotape, I found a measured Regurgitant Jet Area (RJA) of 5.65 cm². This measurement is obtained at the 00:09.19 mark of the apical four-chamber view clip that was obtained by the use of color flow Doppler. This measured RJA does not include any low velocity flow. Rather, this RJA contains

6. (...continued)
regurgitation.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

color which indicate "aliasing," which is characteristic of a high velocity regurgitant jet.

4. The measured Left Atrial Area (LAA) is 27.46 cm², and it is obtained at what appears to be the 00:00.60 mark of the apical four-chamber view.

5. Accordingly, the echocardiogram dated 11/27/01 shows moderate mitral regurgitation with a RJA/LAA ratio of 20.57538%.

* * *

7. In this case, ventricular fibrillation occurred during surgery. The Claimant was shocked or defibrillated two times. The need for the defibrillation of a patient shows definite hemodynamic compromise.

* * *

9. I also reviewed the echocardiogram videotape dated December 14, 2004.

10. This echocardiogram was conducted in accordance with the standards and criteria as outlined in Figenbaum [sic] (1994) and Weyman (1994).

11. On this echocardiogram, I found moderate mitral regurgitation. RJA is measured at 9.57 cm². LAA is measured at 27.32 cm². The RJA/LAA ratio is therefore 35%.

12. In addition, on this echocardiogram, I found pulmonary hypertension secondary to moderate mitral regurgitation, with a peak systolic pulmonary artery pressure of 61 mmHg. measured by Doppler Echocardiography, at rest, utilizing standard procedures and assuming a right atrial pressure of 10 mmHg. (See Question F.2. of the Green Form)

13. In addition, I found an abnormal left atrial supero-inferior systolic dimension of 6.4 cm in the apical four-chamber view, measured by 2-D directed M-mode or 2-D echocardiography with normal sinus rhythm

using sites of measurement recommended by the American Society of Echocardiography (See Question F.5. of the Green Form).

14. Further, I found an ejection fraction that was between 30 and 35%.

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Wang submitted a declaration in which she confirmed her findings at audit. Specifically, Dr. Wang stated:

8. In accordance with the Trust's request, I again reviewed the entirety of Claimant's November 27, 2001 and December 14, 2004 echocardiogram tapes, as well as Claimant's Contest Materials.

* * *

11. With respect to the issue of mitral regurgitation, I affirm my findings at audit, that there is no reasonable medical basis for a finding of moderate mitral regurgitation based upon the November 27, 2001 echocardiogram. At Contest, I again reviewed Claimant's November 27, 2001 echocardiogram and found that the mitral regurgitation is mild and that the area measured includes low velocity flow. I re-measured the regurgitant jet area (RJA) and left atrial area (LAA), arriving at measurements of 4cm and 27cm respectively. Accordingly, I found the RJA/LAA ratio is approximately 14%, which is clearly mild mitral regurgitation.

Further, Claimant's Contest reports an RJA measurement of 5.65 cm² at the 00.09.19 mark on Claimant's November 2001 echocardiogram, and asserts that this RJA yields an RJA/LAA ratio of 20.5%. I measured both the RJA and LAA at this point on Claimant's echocardiogram, and arrived at an LAA of 30 cm². This RJA/LAA of 5.65/30 yields a ratio of 18.7%, which qualifies as only mild mitral regurgitation. Accordingly, I affirm my findings at audit, that Claimant's November 2001 echocardiogram demonstrates

only mild mitral regurgitation, and that there is no reasonable medical basis for a representation of moderate.

* * *

13. With respect to the issue of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise, I affirm my findings at audit, that there is no reasonable medical basis for a finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. While Claimant did have an episode of ventricular fibrillation during surgery, this episode was not spontaneous, but was induced by manipulation of the heart during Claimant's December 15, 2004 coronary artery bypass graft surgery (The 12/15/04 Operative Report indicates, "With initial minimal elevation of the heart so as to expose the distal anterior descending, the patient developed ventricular dysrhythmias and moderate hypotension....") There is no EKG strip documenting this episode of ventricular fibrillation.

Further, while the Claimant was defibrillated, the need for defibrillation in this case is not synonymous with hemodynamic compromise, as Claimant's blood pressure did not drop to a point where hemodynamic compromise occurred. The Operative Report notes only "moderate hemodynamic compromise," and the Anesthesia Record indicates that Claimant's lowest blood pressure reading was 80mm Hg.

Finally, while Claimant experienced a brief episode of post-operative [ventricular tachycardia], this episode required no intervention and did not result in hemodynamic compromise.

Accordingly, I affirm my finding at audit that there is no reasonable medical basis for a finding of ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.

14. Finally, I reviewed the December 14, 2004 echocardiogram tape. After my review, I find that there is no reasonable medical basis for the assertion at Contest that the December 14, 2004 echocardiogram tape demonstrates moderate mitral regurgitation. The mitral regurgitation on this echocardiogram is mild as seen in both the parasternal long axis and apical four-chamber views. In the two-chamber view, the mitral regurgitation appears larger, however, this is due to a shift in the Nyquist baseline (seen only in this view); mitral regurgitation is only mild.

Upon review of the December 14, 2004 echocardiogram tape, I found that Claimant's ejection fraction is 30-35%. I also found mild left atrial enlargement, measuring 4.1cm in the antero-posterior/parasternal long axis view and 6.3cm in the supero-inferior/apical four chamber view.

The Trust then issued a final post-audit determination, again denying the claim. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On July 13, 2007, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7313 (July 13, 2007).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on

December 17, 2007, and the Estate submitted a sur-reply on January 4, 2008. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented is whether the Estate has met its burden in proving that there is a reasonable medical basis for its claim. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of its claim, the Estate argues that there is a reasonable medical basis for Dr. Muttreja's representation that Ms. Drowns suffered from moderate mitral regurgitation. The Estate submitted an additional response that included a supplemental declaration from Dr. Muttreja and a declaration from Martin G. Keane, M.D. Dr. Muttreja stated:

2. I reviewed the Declaration of Zuyue Wang, M.D., dated 4/18/07.

3. According to [her] declaration, Dr. Wang measured both the RJA and the LAA at the 00.09.19 mark. Measurement of the LAA in the same clip used to measure the RJA is not as accurate as finding these measurements in different clips, because the lateral wall is not well visualized in the same clip. If Doppler sampling is used in these views, this is not an uncommon finding.

4. Measurements should be made when all walls traced are clearly identified. The 00.00.60 mark meets this criteria. At this mark, the LAA is measured at 27.46 cm².

5. With the LAA measured at 27.46 cm², the corresponding RJA/LAA ratios are all in the moderate range at the following marks: 00:01.99 (20%), 00:02.72 (22%), 00:05.79 (22%), 00:08.13 (22%), and 00:09.19 (21%).

In addition, Dr. Keane reviewed the December 14, 2004 echocardiogram and found:

4. In my professional opinion, the echocardiogram demonstrates a hemodynamically significant jet of mitral regurgitation in a posteriorly directed jet. This is best visualized in the apical two-chamber view. I have made two measurements of this jet in mid-systole, and have calculated the RJA/LAA based on my measurement of maximal LA area in the apical 4-chamber view (per Singh criteria):

Measurement 1: $5.98 \text{ cm}^2 / 28.87 \text{ cm}^2 = 21\%$
Measurement 2: $7.13 \text{ cm}^2 / 28.87 \text{ cm}^2 = 25\%$
Mean: $= 23\%$

Dr. Keane attached color still frames from the echocardiogram in support of his findings. The Estate also asserts that the Trust conceded the presence of ventricular fibrillation and that Dr. Wang incorrectly imposed a causation requirement when evaluating this claim.

In response, the Trust argues that the Estate must, pursuant to PTO No. 3193, show that Ms. Drowns suffered from medical conditions that qualify her for Level II Matrix Benefits that "co-exist with the ventricular fibrillation" (emphasis in original). The Trust also submits that the declarations of Dr. Muttreja and Dr. Keane do not provide a reasonable medical basis for Dr. Muttreja's finding of moderate mitral regurgitation. With respect to the November 27, 2001 echocardiogram, the Trust contends that Dr. Wang actually measured the RJA and LAA in different frames despite her "misstatement and an inartful choice of words" in her declaration. With respect to the December 14, 2004 echocardiogram, the Trust asserts that "the mitral regurgitation appears larger; however, this is due to a shift in the Nyquist [baseline]." Finally, the Trust argues that there was no reasonable medical basis for Dr. Muttreja's finding that Ms. Drowns suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise because: (1) the only episode of ventricular fibrillation in the

medical records of Ms. Drowns was not "spontaneous, but rather 'was induced by manipulation of the heart during ... surgery;'" and (2) Ms. Drowns was not defibrillated for hemodynamic compromise since "[her] blood pressure did not drop to a point where hemodynamic compromise occurred," despite a notation in the operative report that she had "moderate hemodynamic compromise."

In its sur-reply, the Estate maintains that the requirements of PTO No. 3193 are satisfied because the December 14, 2004 echocardiogram demonstrates conditions necessary for Level II Matrix Benefits and Ms. Drowns suffered from ventricular fibrillation on December 15, 2004. According to the Estate, Dr. Wang's evaluation of the December 14, 2004 echocardiogram is medically unreasonable because the level of decedent's mitral regurgitation must have increased from 18.7%, the RJA/LAA ratio Dr. Wang found in connection with the November 27, 2001 echocardiogram, to at least 20%, the RJA/LAA ratio required for a finding of moderate mitral regurgitation. In support, the Estate argues that the increase in decedent's LAA from 30 cm² on November 27, 2001 to 32 cm² on December 14, 2004 is attributable to "the increased volume pressure from moderate mitral regurgitation."

The Technical Advisor, Dr. Abramson, reviewed the November 27, 2001 and December 14, 2004 echocardiograms submitted by the Estate. Although Dr. Abramson concluded that the November 27, 2001 echocardiogram demonstrated only mild mitral regurgitation, she found moderate mitral regurgitation on the

December 14, 2004 echocardiogram. Specifically, Dr. Abramson stated in her report:

I also reviewed the echocardiogram dated 12/14/04. This study shows a significant deterioration since the previous study of 2001. The left ventricle is now markedly dilated with more regional wall motion abnormalities resulting in severely decreased systolic function. The mitral regurgitation has increased to moderate in all of the apical views. The left atrium is still markedly dilated and mitral annular calcification is still present. The right ventricle is now dilated and hypokinetic with severe tricuspid regurgitation and severe pulmonary hypertension. Dr. Wang stated that the shift in the Nyquist limits in the 2004 echocardiogram accounted for the larger appearance of the mitral regurgitation in that study. Upon intensely reviewing the 2004 study with specific attention to the Nyquist limits, I noticed that the technologist did change the limits in the middle of the study. But, at meter number 0:13:15, the limits were appropriately set at 60 cm/sec during the acquisition of the mitral regurgitation in the apical 4-chamber view. The mitral regurgitation in this view appears moderate. At meter number 13:54, in the apical 2-chamber view, the technologist changed the baseline of the color flow imaging, which resulted in a change of the Nyquist limit for the [mitral regurgitation] to 48 cm/s. While this would make the [mitral regurgitant] jet appear larger than at a usual Nyquist limit, the mitral regurgitation would probably still be moderate in this view if it were obtained with a normal Nyquist limit. Again at meter number 14:18, in the apical long axis view, the color flow baseline was still not in the middle, the Nyquist limit was 36 cm/sec, and the jet of mitral regurgitation appears larger than it would have at a normal Nyquist limit. I think the mitral regurgitation would still be moderate if obtained with a normal Nyquist limit. There is a reasonable medical basis to say that the echocardiogram of 12/14/04 demonstrates moderate mitral

regurgitation. The substantial worsening in the left and right ventricular function, mitral and tricuspid regurgitation, and pulmonary hypertension seen in the 2004 echocardiogram is consistent with chronic, significant coronary artery disease, as demonstrated in her cardiac catheterization on 12/14/04.

After reviewing the entire Show Cause Record, we find that the Estate has established a reasonable medical basis for its claim. As stated previously, a claimant or representative claimant is entitled to Level V benefits if the Diet Drug Recipient qualifies for Level II benefits and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d). A claimant or representative claimant is entitled to Level II benefits for damage to the mitral valve if the Diet Drug Recipient is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See id. § IV.B.2.c.(2)(b).

First, the Estate has established a reasonable medical basis for finding that Ms. Drowns suffered from medical conditions that qualify for the payment of Level II benefits. The attesting physician, Dr. Muttreja, and the Estate's expert, Dr. Keane, reviewed the December 14, 2004 echocardiogram and determined that Ms. Drowns had moderate mitral regurgitation. The Trust, based on the auditing cardiologist's finding that the level of mitral regurgitation seen on the echocardiogram of

December 14, 2004 appeared larger due to "a shift in the Nyquist baseline," challenged the attesting physician's finding. The Estate responded that it is reasonable to conclude that the decedent had moderate mitral regurgitation because her medical condition worsened between the time of her November 27, 2001 echocardiogram and her December 14, 2004 echocardiogram.

In addition, Dr. Abramson reviewed the December 14, 2004 echocardiograms and determined that moderate mitral regurgitation was present. Although Dr. Abramson observed that the mitral regurgitant jet appeared larger at times because of the Nyquist limit settings, she concluded that "I think the mitral regurgitation would still be moderate if obtained with a normal Nyquist limit." Accordingly, she opined that "[t]here is a reasonable medical basis to say that the echocardiogram of 12/14/04 demonstrates moderate mitral regurgitation."⁹

As stated above, moderate or greater mitral regurgitation is present where the RJA in any apical view is equal to or greater than 20% of the LAA. See Settlement Agreement § I.22. Here, Dr. Muttreja, Dr. Keane, and Dr. Abramson each found that the December 14, 2004 echocardiogram demonstrated an RJA/LAA ratio greater than 20%. Under these circumstances, the Estate has met its burden in establishing a reasonable medical basis for finding that Ms. Drowns had moderate mitral regurgitation. As the auditing cardiologist confirmed

9. Despite an opportunity to do so, the Trust did not submit a response to the Technical Advisor Report. See Audit Rule 34.

that the December 14, 2004 echocardiogram demonstrated an abnormal left atrial dimension and a reduced ejection fraction less than or equal to 60%, each of which is a complicating factor for a mitral valve claim, the Estate qualifies for Level II benefits. See Settlement Agreement §§ IV.B.2.c.(2)(b)ii) & iv).

Second, we find that the Estate has met its burden of proving that Ms. Drowns suffered from ventricular fibrillation. See id. § IV.B.2.c.(5)(d). The Trust concedes that claimant suffered from ventricular fibrillation. According to the Trust, however, the ventricular fibrillation Ms. Drowns experienced was "not spontaneous, but rather 'was induced by manipulation of the heart during ... surgery.'"

The Estate argues that the Trust is improperly requiring proof of causation, stating that "[t]here simply is not a causation question; the question simply asks whether or not the ventricular fibrillation occurred." We agree. Causation generally is not at issue in resolving claims for Matrix Benefits. Rather, claimants or representative claimants must show that Diet Drug Recipients meet the objective requirements set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which

matrix level they qualify for and the age at which that qualification occurred

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97.

Section IV.B.2.c.(5)(d) of the Settlement Agreement does not require any proof that the Diet Drug Recipient suffered from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise as a result of Diet Drug use. We must apply the Settlement Agreement as written. Accordingly, the Trust's assertion that an individual must experience one of these conditions spontaneously is misplaced.

We also disagree with the Trust that a claimant is required to prove that ventricular fibrillation resulted in hemodynamic compromise. To the extent Section IV.B.2.c.(5)(d) of the Settlement Agreement is ambiguous, the doctrine of the last antecedent, a canon of statutory construction, is instructive. The doctrine of the last antecedent provides that "qualifying words, phrases, and clauses are to be applied to the words or phrase immediately preceding, and are not to be construed as extending to and including others more remote." Resolution Trust Corp. v. Nernberg, 3 F.3d 62, 65 (3d Cir. 1993) (internal quotation and citation omitted). Failure to use a comma can

limit application of qualifying language to the word or phrase immediately preceding it. Nat'l Surety Corp. v. Midland Bank, 551 F.2d 21, 34 (3d Cir. 1977). Here, the Settlement Agreement reads: "[t]he individual ... suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise." See Settlement Agreement § IV.B.2.c. (5) (d). The context of the language, the doctrine of the last antecedent, and the lack of a comma separating the qualifying language from the previous phrases leads to the conclusion that a claimant must suffer from either ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. In other words, the phrase "which results in hemodynamic compromise" only qualifies sustained ventricular tachycardia. This interpretation is supported by reference to other similar provisions. See, e.g., id. § IV.B.2.c. (2) (b)v) (defining arrhythmias as "chronic atrial fibrillation/flutter that cannot be converted to normal sinus rhythm, or atrial fibrillation/flutter requiring ongoing medical therapy, any of which are associated with left atrial enlargement") (emphasis added).

Finally, we reject the Trust's argument that the Estate has not satisfied the requirements of the Settlement Agreement and PTO No. 3193. As noted above, the December 14, 2004 echocardiogram demonstrated conditions consistent with Matrix Level II and, as conceded by the Trust, Ms. Drowns suffered from ventricular fibrillation on December 15, 2004. We find that on

these specific facts, the Estate has established that the criteria for Matrix Level II benefits and ventricular fibrillation existed concurrently.

For the foregoing reasons, we conclude that the Estate has met its burden of proving that there is a reasonable medical basis for its claim and is consequently entitled to Matrix B-1, Level V benefits. Therefore, we will reverse the Trust's denial of the Estate's claim for Matrix Benefits.